UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,002	03/19/2002	Jean-Jacques Caboche	0600-1031	5740

466 7590 02/25/2010

YOUNG & THOMPSON
209 Madison Street
Suite 500
Alexandria, VA 22314

EXAMINER	
OLSON, ERIC	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
02/25/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/030,002	CABOCHE ET AL.	
	Examiner	Art Unit	
	ERIC S. OLSON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-24 and 31-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22,31-47 and 49* is/are rejected.

7)☒ Claim(s) *23,24,48 and 50* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted November 9, 2009 wherein new claims 45-50 are introduced. This application is a national stage application of PCT/FR00/01109, filed April 26, 2000, which claims priority to foreign application FR99-05523, filed April 30, 1999.

Claims 19-24 and 31-50 are pending in this application.

Claims 19-24 and 31-50 as amended are examined on the merits herein.

Applicant's arguments, submitted November 9, 2009, with respect to the rejection of instant claims 19-24 and 31-44 under 35 USC 112, first paragraph, for lacking written description for the limitation that the branched polymers comprise an additional chain of glucose units at every 10 to 14 glucose units, have been fully considered and found to be persuasive to remove the rejection as one skilled in the art would recognize that the known branching enzymes used by Applicant would introduce additional glucose chains at every 10 to 14 glucose units. Therefore the rejection is withdrawn.

Applicant's arguments, submitted November 9, 2009, with respect to the rejection of instant claims 19-24 and 39-42 under 35 USC 112, first paragraph, for lacking enablement for all possible starch branching enzymes, have been fully considered and found to be persuasive to remove the rejection as Applicant has successfully demonstrated that branching enzymes are a recognized class of synthetic reagents that would be available to one skilled in the art. Therefore the rejection is withdrawn.

The following rejections of record in the previous action are maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-37 and 39-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). In the present instance, claims 31, 34, 39, and 42 recite the broad recitation between 2.5 and 10% of α-1,6 glucosidic bonds, and the claim also recites "wherein said soluble branched polymers of glucose in isolated and purified form comprise, at every 10 to 14 glucose units, an additional chain of glucose units," which is the narrower statement of the range/limitation. This narrow range of one side chain every 10 to 14 glucose units would, as the branching enzyme introduces side chains as α-1,6 bonds, indicate that the branched starch contains between about 6.7 and 9.1% α-1,6 glucosidic bonds, which is significantly narrower than the broad limitation recited in said claims.

Furthermore the dependent claims 32, 36, and 37 insert additional limitations that limit the amount of α-1,6 glucosidic bonds of 2-5-5% or 5-10%. Both of these ranges

similarly include embodiments outside of the range of 6.7-9.1%, and therefore lack antecedent basis in the base claims.

Response to Argument: Applicant's arguments, submitted November 9, 2009, with respect to the above ground of rejection have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that these two limitations are separate limitations and that the additional chains of glucose residues being added are additional to the 2.5-10% of naturally occurring α-1,6 glucosidic bonds. Firstly, regarding the product claims 31-37, a product claim is drawn to a specific physical composition of matter regardless of its history or method of manufacture. For such a product there is no distinction between an α-1,6 bond or side chain that is naturally occurring in the molecule and one which has been added by further chemical manipulation. Therefore, the limitation "between 2.5 and 10% of α-1,6 glucosidic bonds" includes all such bonds in the polymer, both those naturally occurring in the polymer as isolated from its biological source and those added later by the action of a branching enzyme *in vitro*.

Regarding the limitation, "at every 10 to 14 glucose units, an additional chain of glucose units," the broadest reasonable interpretation of this limitation is that the term "additional chain" means any chain of glucose units beyond the main chain. (i.e. a side chain) This limitation similarly cannot distinguish between side chains present in the native starch molecule (e.g. amylopectin) and those introduced by further chemical transformations. Applicant's distinction between those bonds or chains previously present in the starch and those added by additional modifications has no basis in the

claim language as actually presented and is not necessarily how one skilled in the art would interpret the claims.

Process claims 39-44 are defined by the product they produce. Therefore the limitations are treated in the same manner as the product limitations discussed above in claims 31-37.

Regarding the actual structure of the starch molecule described in the claims, a molecule having the limitation, “wherein the branched polymers of glucose comprise, at every 10 to 14 glucose units, an additional chain of glucose units,” would have an approximate structure as shown in Figure 1 below:

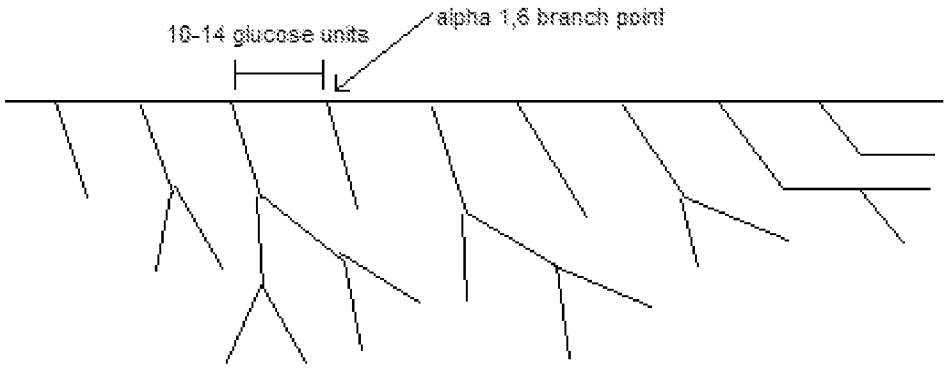

Figure 1 - Diagram of branched starch molecule described in the claims

This polymer is a starch polymer having α-1,4 glucosidic bonds, wherein an additional poly α-1,4 glucose side chain has been attached every 10-14 glucose units. Because the starch branching enzymes described in the specification introduce the side chains as α-1,6 bonds, each branch point adds an α-1,6 bond to the molecule. Therefore, for every 10-14 α-1,4 linkages in the polymer, there will be an additional α-

1,6 linkage at the required branch point where the side chain is introduced. This means that the ratio of α-1,6 to α-1,4 bonds will be between 1:10 and 1:14. Calculated as percentages, these ratios come to between about 9.1% and about 6.7%, as described in the body of the rejection.

For these reasons the rejection is deemed proper and made **FINAL**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19-22, 31-47, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (US patent 4454161, of record in previous office action) in view of Senkeleski et al. (US patent 5562937, of record in previous action) in view of Sandström et al. (PCT international publication WO95/22562, of record in previous action, also published as Brynolf et al. (US patent 5929052, of record in previous action)

Okada et al. discloses a branched alpha-glucose polymer (starch) produced by the activity of a branching enzyme, for example an animal, plant, or microorganism branching enzyme in a starch such as amylopectin. (column 1 lines 47-63) A gelatinized solution of the starch is subjected to the action of the branching enzyme and then used, after concentration and/or drying, in food products. (column 2, lines 5-20) A bacillus branching enzyme is reported (column 5, lines 15-23) having an optimal temperature of

about 25C and being stable up to about 45C. (column 6 lines 39-49) an *E. coli* branching enzyme is also reported. (column 8 lines 1-25) These starches display a reduced propensity for retrogradation. (column 2, lines 21-31) Okada et al. does not disclose a method in which the starch is gelatinized by a treatment at over 130^{O}C and 3.5 bars as recited in the instant claims. Okada et al. also does not explicitly disclose a method in which the amount of branching enzyme is between 50-2000 units and the reaction is carried out at exactly 30^{O}C. Okada et al. does not explicitly disclose a composition having a branch point at every 10-14 glucose units, or one having the molecular weight, percent of alpha 1,6 bonds, or reducing sugar content recited in the instant claims.

Senkeleski et al. discloses a method for digesting waxy starch with beta-amylase. (column 1, lines 40-58) The starch, in order to be processed in this manner, is first steam cooked at a temperature of 120^{O}C to 170^{O}C at a pressure of 60-80 psi, which is equivalent to about 4.1-5.5 bar.

Sandström et al. discloses a branched starch (alpha-glucose polymer) having a molecular weight ranging from 1.5x10^{4} to 10^{7} daltons, corresponding to the limitations in instant claim 31. (p. 3, lines 16-24) These starches have a branching degree of about 2-8%, preferably 3-7%. (p. 4, lines 1-3) A starch with this molecular weight will possess less than 1% reducing sugars, as there will be only one reducing end per molecule. The starch is particularly stable in solution, (p. 2 lines 25-31) and will therefore have a low tendency to retrograde in solution. These molecules are also considered to possess the claimed viscosity of at most 5000 cP in view of the fact that they possess

the same structural characteristics (size, degree of branching) as those described in the instant specification. (for example p. 21, table II of the instant specification) It is noted that the starches of Sandström et al. differ from the claimed invention in that they possess beta-glycosidic linkages as a result of the specific method of acid treatment used to increase the branching degree.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the method of Okada et al. in view of Senkeleski et al. to produce a branched product as described by Sandström et al., having the same molecular weight and degree of branching but lacking beta-glycosidic bonds. One of ordinary skill in the art would have recognized that the enzymatic treatment of Okada et al. in view of Senkeleski et al. produces the same result, namely increased branching, as the acid treatment of Sandström et al., and that the two treatments are therefore interchangeable. With regard to the presence of beta-glycosidic bonds in the compounds of Sandström et al., this structural feature is an incidental result of the particular acid treatment used, and is not seen to be necessary for the desired properties, namely stability and reduced osmolality, present in the starches of Sandström et al. One of ordinary skill in the art would reasonably have expected success because the method of Okada et al. in view of Senkeleski et al. is already seen to be useful for increasing the branching degree of a starch.

Furthermore, it would have been obvious to one of ordinary skill in the art to optimize the various characteristics of the starch of Sandström et al., such as degree of branching and molecular weight, to arrive at the values discussed in instant claims 32,

36, and 37. One of ordinary skill in the art would have been able to choose optimal values for these experimental parameters through a simple process of routine optimization, and would clearly have recognized these structural properties to be result-effective variables that could be varied to produce the desired solution properties in the final product. Note that the new limitation that the branched polysaccharide have a branch point at every 10-14 glucose units is equivalent to a composition of between 6.7-9.1% α-1,6 bonds, considering that naturally occurring, enzymatically synthesized starches are polymers of α-1,4 bonds with branch points of α-1,6 bonds.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted November 9, 2009, with respect to the above ground of rejection have been fully considered and not found persuasive to remove the rejection. Applicant argues that the teachings of Okada and Senkeleski cannot be combined because Okada et al. is directed toward increasing the size of the starch molecules while Senkeleski is directed toward cutting the starch molecule into monosaccharides and disaccharides.

However, regardless of the differences in the enzymatic reaction being performed, both Okada and Senkeleski disclose methods comprising gelatinizing a starch and treating it with an enzyme. Nothing in the disclosure of Senkeleski or elsewhere in the art indicates that the gelatinization step disclosed by Senkeleski is specific to the particular enzymatic hydrolysis reaction disclosed in the reference. Rather one of ordinary skill in the art would see Senkeleski as teaching both a particular gelatinization step and a particular enzymatic hydrolysis step, and would consider the

gelatinization step as being usable in any situation where gelatinization of a starch is called for. Given that Okada discloses the desirability of gelatinizing the starch before treatment with a branching enzyme, one of ordinary skill in the art would consider any mention of a gelatinization technique in the art to be usable for this purpose.

While it is true that a prior art reference must be considered as a whole, nothing in the reference taken as a whole teaches away from using high pressure steam gelatinization to gelatinize starches for other enzymatic reactions. Senkeleski teaches that the hydrolysis of the starch results from the treatment with beta amylase, not from high pressure steam gelatinization. Therefore Senkeleski teaches away from adding a beta amylase treatment to the present invention, but not from adding a high pressure steam gelatinization step. The mere fact that a particular element of a prior art reference is not combinable with a primary reference does not place the entire reference off limits for combination. Rather, one of ordinary skill in the art would have been able to take individual process steps from the prior art disclosure and use them in a different method, without being bound to recreate the entire method of the prior art.

Regarding the disclosure of Sandström, Applicant argues that there is no finding of fact to support the conclusion that one of ordinary skill in the art would have been motivated to make a starch having the molecular weight and branching degree described by Sandström but would not have regarded the presence of beta glucosidic bonds as being important to the invention disclosed by Sandström. However, one of ordinary skill in the art would, from considering the disclosure of Sandström, conclude that molecular weight and branching degree are critical elements for the function of said

starch, while the non-native stereochemistry of the glucosidic linkages is an incidental feature of the chemical treatment used. In particular, the statement of the invention in p. 2 lines 25-31 describe that the inventive starch has a molecular weight of between about 15000 and 10000000 and is heavily branched but makes no mention of beta glucosidic linkages. The claims of both Sandström and equivalent US patent 5929052 also mention specific molecular weights and degrees of branching but are silent regarding beta glucosidic linkages. For these reasons one of ordinary skill in the art would not regard the presence of beta glucosidic linkages as being an essential or even an important element of the polysaccharides described by Sandström.

For these reasons the rejection is deemed proper and made **FINAL**.

Conclusion

Claims 19-22, 31-47, and 49 are rejected. Claims 23, 24, 48, and 50 are objected to for depending from a rejected base claim but would be allowable if rewritten in independent form incorporating all the limitations of the rejected base claim and any intervening claims. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/

Examiner, Art Unit 1623
2/17/2010